OCT 31 2000

K002810

510(k) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of SMDA and 21CFR § 807.92

Submitted by:

Nordiska Dental AB
Box 1082
S-262 21 Ängelholm
Sweden

Managing Director: Lars Bengtsson
Fax Number: (+46) 461 44 33 99

Initial Distributor:

Nordic Dental, Inc.
P.O. Box 435
Lynwood, WA 98046

Managing Director: Richard Kirschner
Phone: 425-745-2584
Fax: 425-745-2584

Date Prepared: September 1, 2000

Device Name:

Proprietary Name: **ANA 3000 SM Non Gamma 2 Modified Spherical Dental Alloy**

Common Name: Dental Amalgam

Classification: Class II; EJJ; Alloy, Amalgam

Identification of Predicate Devices

- **L. D. Caulk Co.**, Valiant, 510(k) number K801690.
- **Wykle Research, Inc.**, Cupralloy, 510(k) number K952670.

Device Description:

ANA 3000 SM Non Gamma 2 Modified Spherical Dental Alloy is an all automozied product, a combination of a modified spherical and irregular powder particles. It provides an amalgam with the high early compressive strengths characteristics. It shows a balanced

expansion after 24 hours while other spherical and admix alloys undergo a substantial contraction. It has the further benefit of very low leakage.

Indication for Use:

ANA 3000 SM Non Gamma 2 Modified Spherical Dental Alloy is a dental alloy designed for stress-bearing Class I and Class 2 restorations.

Technological Characteristics

ANA 3000 SM Non Gamma 2 Modified Spherical Dental Alloy showed on testing all the better properties of both spherical and ad-mixed alloys, eliminating poor features of each.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2000

Nordiska Dental AB
C/O Mr. Richard Kirschner
Managing Director
Nordic Dental, Incorporated
P.O. Box 435
Lynwood, Washington 98046

Re: K002810
Trade Name: ANA 3000 SM Non Gamma 2 Modified Spherical Dental Alloy
Regulatory Class: II
Product Code: EJJ
Dated: September 1, 2000
Received: September 8, 2000

Dear Mr. Kirschner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Include the following "Indications For Use" page that contains the applicant's name, name of the device and the intended use of the device. The information, data and labeling claims in the entire the 510(k) submission must support and agree with the "indications for use" statement.
*For a new submission, do NOT fill in the 510(k) number blank.

INDICATIONS FOR USE

Applicant:. Nordiska Dental AB

510(k) Number (if known): N/A*

Device Name: **ANA 3000 SM Non Gamma 2 Modified Spherical Dental Alloy**

Indications For Use:

ANA 3000 SM Non Gamma 2 Modifed Spherical Dental Alloy is a dental alloy designed for stress-bearing Class I and Class 2 restorations.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter _____
Per 21 CFR 801.109

Sandra L. Shive, DMD for MSR.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002810